

TESTIMONY OF CONNECTICUT HOSPITAL ASSOCIATION SUBMITTED TO THE GENERAL LAW COMMITTEE Tuesday, February 25, 2014

HB 5262, An Act Concerning The Pharmacy Practice Act And Counterfeit Drugs

The Connecticut Hospital Association (CHA) appreciates this opportunity to submit testimony concerning HB 5262, An Act Concerning The Pharmacy Practice Act And Counterfeit Drugs. CHA opposes the bill as written.

Before outlining our concerns, it's important to detail the critical role hospitals play in the health and quality of life of our communities. All of our lives have, in some way, been touched by a hospital: through the birth of a child, a life saved by prompt action in an emergency room, or the compassionate end-of-life care for someone we love. Or perhaps our son, daughter, husband, wife, or friend works for, or is a volunteer at, a Connecticut hospital.

Hospitals treat everyone who comes through their doors 24 hours a day, regardless of ability to pay. In 2012, Connecticut hospitals provided nearly \$225 million in free services for those who could not afford to pay.

Connecticut hospitals are committed to initiatives that improve access to safe, high-quality care. They are ensuring that safety is reinforced as the most important focus—the foundation on which all hospital work is done. Connecticut hospitals launched the first statewide initiative in the country to become high reliability organizations, creating cultures with a relentless focus on safety and a goal to eliminate all preventable harm. This program is saving lives.

Generations of Connecticut families have trusted Connecticut hospitals to provide care we can count on.

HB 5262 contains important changes to various pharmacy laws designed to protect patients. CHA supports these efforts to protect patients, but we wish to set forth some necessary clarifications to avoid unintended negative consequences for patient care.

Section 1 of HB 5262 seeks to clarify how a prescribing practitioner can require a pharmacist to fill a prescription with a brand-name-only drug; it prohibits a pharmacist from making a generic substitution. We have concerns about the implementation of this requirement. For this to function properly, electronic prescribing systems will need to be reprogrammed, and physicians and other prescribers will need to be retrained. We ask that more time be allowed for implementation by making the effective date January 1, 2015 instead of July 1, 2014.

Without the additional time, we are concerned that some patients may not have access to the drugs they need.

Sections 2 through 6 of HB 5262 are targeted at compounding and out-of-state pharmacies that may not have sufficient oversight or controls to ensure safe drug preparation and safe manufacturing. Over the last year, Connecticut patients and Connecticut hospitals were faced with alarming situations caused by out-of-state compounding pharmacies that delivered inferior and, in some cases, dangerous products. We fully support the Department of Consumer Protection moving forward with efforts to rein in pharmacies that do not meet basic levels of safe practice. But CHA believes that the bill as written would have the unintended consequence of applying similar controls to hospital pharmacies, which have not been the source of any such problems.

Specifically, we believe that hospital pharmacies should not be required to obtain a manufacturer's license, or be regulated in the same manner as compounding pharmacies, when preparing compounded preparations for their own use and their own patients. To avoid such over-inclusion, we respectfully ask that an exception be made for hospital pharmacy by making the following change to Section 2(a)(1):

(1) "Sterile compounding pharmacy" means a pharmacy, an institutional pharmacy within a facility licensed pursuant to section 19a-490 of the general statutes <u>other than a hospital</u>, or a nonresident pharmacy as defined in section 20-627 of the general statutes, as amended by this act, that dispenses or compounds sterile pharmaceuticals; and

We also request adding the following sentence to the end of Section 6(a):

For the purposes of this section, a pharmacy within a Connecticut licensed hospital shall not be considered a compounding pharmacy.

Additionally, HB 5262 seeks to increase oversight of companies that trade in counterfeit substances, including mislabeled or falsely identified drugs. CHA supports giving the Department of Consumer Protection the authority to investigate and, if necessary, take action against companies that intentionally falsify labels or pass along counterfeit substances, including drugs.

CHA believes, however, that such a law should not also apply to the innocent victims who may be duped by these malevolent actors. Under Section 8 of HB 5262, a pharmacy, physician, or hospital that dispenses or purchases a drug that is falsely labeled or otherwise counterfeit would be in violation of the law – despite the fact that the pharmacy, physician, or hospital was an innocent victim of the fraud. To remedy this, we suggest that Section 8 of the bill be changed.

Section 8 of HB 5262 is designed to expand on a law passed in the 2013 Legislative Session concerning General Statutes Section 21a-432, which included the "knowingly" element to be in violation of the prohibition against counterfeit substances. We believe that, without restoring the "knowingly" element, Section 8 of HB 5262 is particularly unfair to unsuspecting victims of fraud.

CHA respectfully requests that Section 8(b) of HB 5262 be amended as follows.

(b) No person shall **knowingly** purchase for resale, sell, offer for sale or deliver in any manner a counterfeit substance.

Thank you for your consideration of our position. For additional information, contact CHA Government Relations at (203) 294-7310.